REMARKS

It has come to the attention of the undersigned attorney that there is a typographical error in the table on page 6 of the Application. Titanium dioxide was inadvertently mischaracterized as being an organic sunscreen. Titanium dioxide is, of course, an inorganic material, as more fully set forth in paragraph 0005 of the Application. It is recognized that 37 CFR § 1.121(b) does not explicitly provide for submission of substitute pages. However, in this case the page in question consists of a single table, not a numbered paragraph. It is believed, therefore, that a substitute page is appropriate in this instance. However, if a substitute page cannot be entered into the record, it is requested that the Examiner, by Examiner's amendment, change "organic" to "inorganic" in the column adjacent to "Tioveil AQ".

The substantive amendments to the claims are for the purpose of overcoming the rejections under 35 USC §§ 103 and 112. In addition, certain editorial corrections are being made. These corrections include an insertion of previously-omitted subject matter into Claim 20. Claim 20 was intended as a replacement for original Claim 3 but, when submitted, a portion was inadvertently left out.

REJECTION UNDER 35 USC § 112

Claim 16 has been rejected under the second paragraph of 35 USC § 112 on the ground of indefiniteness. As suggested by the Examiner, the foregoing amendment changes "including" to "comprising". By making this change, Applicants do not intend to narrow the scope of the claimed subject matter.

REJECTION UNDER 35 USC § 103(a)

All the claims have been rejected as obvious over Stewart US Patents Nos. 5,916,541, 6,159,452 and 6,284,227. Stewart '227 is a CIP of Stewart '452 which, in turn, is a CIP of Stewart '541. Stewart '227, having issued on an application filed on 12

December 2000 is not available as a reference for any material not previously disclosed in Stewart '541 or Stewart '452. The instant application has an international filing date of 11 January 2000 and Applicants' effective filing date, based on their British priority application, is 14 January 1999. As far as Stewart '541 and Stewart '452 are concerned, it is noted that the written descriptions in Stewart '452 contains all of the material in Stewart '541. The "new material" in Stewart '452 concerns only some of the specific insect repellents and is not relevant to any of the issues raised by the Examiner. Furthermore, it is apparent that, in referring to the prior art, the Examiner is referring to various passages in Stewart '541. Accordingly, the rejection will be discussed in terms of Stewart '541 ("Stewart").

Applicants' invention is directed to a sunscreen composition that also includes one or more insect repellents. Compositions comprising both a sunscreen and an insect repellent are well known in the art. However, Applicants have discovered that an exceptionally stable sunscreen composition that includes one or more insect repellents is obtained through a new method of manufacture. Essentially, the manufacturing process involves the steps of: preparing an aqueous phase that includes a thickener; separately preparing an oil phase that includes at least two emulsifiers, at least one insect repellent and at least one organic UV sunscreening agent; combining the two phases to form an oil-in-water emulsion; and adding at least one inorganic sunscreening agent to the emulsion. A critical feature in Applicants' process is that, by delaying the incorporation of the inorganic sunscreening agent until after the oil-in-water emulsion is formed, the sun protection factor (SPF) of the final composition is stabilized. All of the claims in this Application, as now amended, specify clearly that the emulsion is an oil-in-water emulsion and that the inorganic sunscreening agents are added to said emulsion.

The prior art, including Stewart, teaches sunscreen compositions that also include insect repellents, recognizes that said compositions can include more than one sunscreening agent and recognizes that the sunscreening agents can include titanium

dioxide and zinc oxide as inorganic sunscreening agents. However, what the prior art does not recognize is that improved sunscreening compositions are obtained if, instead of including the inorganic sunscreening agent with the organic sunscreening agents in the oil phase, the inorganic sunscreening agent is not added until the aqueous phase and the oil phase have been emulsified.

The Examiner notes correctly that zinc oxide and titanium dioxide are specifically mentioned in Stewart as sunscreening agents and the paragraph beginning at column 4, line 46, can be understood as disclosing the use of a combination of sunscreening agents in the disclosed compositions. However, the reference that does not disclose or even hint at the possibility that, in manufacturing the disclosed compositions, the various sunscreening agents should be added in different steps in the manufacturing process. There is nothing in Stewart's specification or claims that would support the concept of adding different sunscreening agents at different points in the process, much less the concept of adding organic sunscreening agents at one point and adding inorganic sunscreening agents at a later point.

A reference must be read for what it fairly discloses. Stewart can be fairly read as disclosing a sunscreen composition that includes multiple sunscreening agents. However, it cannot be read as disclosing a sunscreening composition that is manufactured by a method that involves a multi-step process where different sunscreening agents are added at different points in the process. The sunscreening agents that can be used in the Stewart composition are disclosed only in the paragraph beginning at column 4, line 46. Later in the Stewart references, there are five specific examples which teach methods for preparing the Stewart compositions. In each of these five methods, the sunscreening agents are all in Phase B. Phase B, an "oil" phase, is - in all five examples - emulsified with the aqueous phase, Phase A. In each of the examples, further ingredients are added to the emulsion but none of these ingredients are sunscreening agents. Thus, Stewart cannot be fairly read as disclosing the concept that sunscreening agents should be added

at different points in the manufacturing process. Applicants' claimed process not only provides that different sunscreening agents should be added at different steps in the process, but also requires that the organic sunscreening agents be added to the oil phase and that the inorganic sunscreening agents not be added until after the emulsion is formed. Neither of these concepts can be derived from anything in the Stewart reference.

As Applicants' have noted at page 3, line 27, the order of addition of ingredients affects the sun protection factor (SPF) of the final composition. More specifically, if the inorganic sunscreening agents are added after the emulsion is formed, the SPF of the final composition remains substantially constant, rather than deteriorating on storage.

The specific examples in Stewart do not include any compositions that contain titanium dioxide or zinc oxide, the two inorganic sunscreening agents mentioned elsewhere in the reference. Stewart's process calls for all of the sunscreening agents to be added to the oil phase, Phase B, and there is a good reason not to include inorganic sunscreening agents. It is inherently difficult to stabilize a suspension of inorganic particles, such as titanium dioxide, in oil. It would be very difficult to prevent inorganic particles suspended in an oil emulsion from touching each other and sticking together. Without wishing to be bound by any particular theory, Applicants believe that particles of titanium dioxide within the oil phase of Stewart's emulsion would be very likely to clump together. Such clumping would increase with time and the SPF of the composition would, as result, decrease with time. When such a sunscreen composition is applied to the skin, the clumped inorganic particles would be deposited on the skin in clumps. Because some of the clumped particles would be on top of other particles the particle distribution on the skin becomes uneven. Thus, the protection of the skin is reduced relative to the protection which would be provided by more uniform distribution of particles. As a consequence, the measured SPF would be lower.

Applicants are claiming methods for producing sunscreen compositions that also comprise insect repellents and are claiming compositions made by these methods. In

contrast to what would occur in the Stewart process if inorganic sunscreen particles were added to the oil phase, the organic particles in Applicant's method are added to the outer continuous phase of the oil-in-water emulsion, rather than to the discreet oil phase of the emulsion. The colloidal stability of these inorganic particles in water is inherently very high, and the inorganic sunscreen particles in the water phase remain evenly distributed throughout said phase. Thus, when applied to the skin, the sunscreen composition of the present invention provides a uniform distribution of inorganic particles on the skin. As pointed out by Applicants on page 1, line 22, the function of the inorganic sunscreening agents is to scatter UV light. Having an even distribution of such agents on the skin is essential in fulfilling this function.

For the foregoing reasons, it is believed that the rejection over Stewart should be withdrawn.

INFORMATION DISCLOSURE STATEMENT

On 17 September 2001, Applicant filed an Information Disclosure Statement. This was not acknowledged by the Examiner. In the event that the Information Disclosure Statement and the cited references are not the file, Applicants would be happy to resubmit these documents.

CONCLUSION

In view of the foregoing amendment and these remarks, it is believed that all claims in this Application are in condition for allowance. Favorable action is therefore requested.

Respectfully submitted,

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TABLE 1.

INGREDIENT (SUPPLIER)	*PURPOSE*
DEET (MGK) N,N-diethyl-m-toluamide	Mosquito repellent
MGK -326 (MGK) dipropyl pyridine-2,5-dicarboxylate 99%	Fly repellent
Parsol MCX (Givaudan) octyl methoxycinnamate 98%	UVB filter, organic sunscreen
Benzophenone -3 (Aceto Corp.) oxybenzone 98%	UVA/B filter, organic sunscreen
Tioveil AQ micronised titanium dioxide 40%	UVA/B filter, inorganic sunscreen
Cithrol GMS A/S (Croda) glycerol monostearate	emulsifier
Volpo S20 (Croda) ethoxy (20) stearyl alcohol	emulsifier
Crodacol CS70 (Croda) cetoaryl alcohol 35/65	emulsifier
Polawax GP 200 (Croda) blend of cetostearyl alcohol and PEG stearate	emulsifier
Antaron WP-660 (ISP) 2-pyrrolidinone, 1-ethenyl polymer with 1-triacontene	film former
Silicone DC 200/500 (Dow Corning) silicone oil 200/500	emollient
Carbopol 940 (B F Goodrich) carboxyl polymethylene	thickener
Aloe Vera powder 1:200	moisturiser
Sequestrene NA2 disodium EDTA	chelating agent
Triethamolamine H/H (Union Carbide)	neutraliser
Germaben II-E	preservative
Kokoda 6463	perfume
Water	diluent